



BONESUPPORT HOLDING AB (publ) announces that the patient enrolment schedule for the ongoing FORTIFY study is extended

Lund, Sweden, 10.00 am CET, 21 August 2019 – BONESUPPORT[™], listed on Nasdaq Stockholm - an emerging leader in orthobiologics for the management of bone voids, announces that the patient enrollment schedule for the ongoing FORTIFY study is extended.

Providing strong clinical evidence in support of its core technology, CERAMENT, is one of the cornerstones of BONESUPPORT's strategy. The FORTIFY study was initiated in 2017 with the purpose to evaluate the safety and efficacy of CERAMENT G as part of surgical repair of open diaphyseal tibial fractures versus standard of care. The results of the study are intended to support the FDA Pre-Market Approval (PMA) application for CERAMENT G in the US.

The study is designed to include up to 230 patients at clinics in the US and Europe and, like other trauma studies, the enrollment rate is difficult to predict. It has previously been announced that we expected the patient recruitment to be completed by the end of 2019, followed by a PMA application to the FDA at the end of 2020.

BONESUPPORT has received updated data regarding the patient enrollment to the FORTIFY study and can conclude that the patient recruitment phase is expected to be extended by 6-9 months. Patient follow-up is 12 months and the FDA registration application is hence estimated to take place in late 2021.

About BONESUPPORT™

BONESUPPORT (Nasdaq Stockholm: BONEX) develops and commercializes innovative injectable bio-ceramic bone graft substitutes that remodel to the patient's own bone and have the capability of eluting drugs. BONESUPPORT's bone graft substitutes are based on the patented technology platform CERAMENT. The company is conducting several clinical studies to further demonstrate the clinical and health economic benefits its products deliver and a Premarket approval filing with the FDA (USA) for its gentamicin eluting product is planned in 2021. The company is based in Lund, Sweden, and the net sales amounted to SEK 97 million in 2018. Please visit www.bonesupport.com for more information.

BONESUPPORT and CERAMENT are registered trademarks of BONESUPPORT AB.

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Press Release



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This information is such information as BONESUPPORT HOLDING AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 10:00 CET on August 21, 2019.